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Department of Health Services: Reporting and Inspection Requirements

General Acute Care Hospitals, Psychiatric Hospitals or Specialty Hospitals

Legislation enacted 2005-2006 Session

Effective January 1, 2007 SB 1301, Chapter 647 is an act to add Section 1279.1, 1279.2, 1279.3 and 1280.4 to, the Health and Safety Code, relating to health facilities. The act among other provisions, would require the Department of Health Services to ensure that periodic inspection of health facilities are not announced, and inspected for compliance with state laws and regulations, no less that once every three years. If an inspection is conducted jointly with another entity that provides notification in advance, the Department will be required to conduct additional inspection that is not announced to the health facility.

The act, in addition requires a general acute care hospital, psychiatric hospital, or special hospital to report to the Department any adverse event within 5 days of its discovery. If the adverse event is an urgent threat to the welfare, safety or health of patients, personnel, or visitors, the event must be reported to the Department within 24 hours of its discovery. It requires DHS to conduct an onsite inspection or investigation within 48 hours of 2 business days of a complaint involving the threat of imminent danger of death or serious bodily harm. The outcomes of the inspections would be required to be posted on the Departments Internet Web Site. It would also authorize the Department to assess civil penalties against a license for failure to report an adverse events.

The act adds Section 1279.1, 1279.2, 1279.2 and 1280.4, to the Health and Safety Code:

SECTION 1. Section 1279.1 is added to the Health and Safety Code,to read:
1279.1. (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.
(b) For purposes of this section, "adverse event" includes any of the following:
(1) Surgical events, including the following:
(A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.
(B) Surgery performed on the wrong patient.

(C) The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(E) Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(2) Product or device events, including the following:

(A) Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

(B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

(C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(3) Patient protection events, including the following:

(A) An infant discharged to the wrong person.

(B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decisionmaking capacity.

(C) A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.

(4) Care management events, including the following:

(A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(D) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.

(E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes

of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.

(F) A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

(G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

(5) Environmental events, including the following:

(A) A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.

(B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

(C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

(D) A patient death associated with a fall while being cared for in a health facility.

(E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

(6) Criminal events, including the following:

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(B) The abduction of a patient of any age.

(C) The sexual assault on a patient within or on the grounds of a health facility.

(D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

(c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

(d) "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than 7 days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

(e) Nothing in this section shall be interpreted to change or otherwise affect hospital reporting requirements regarding reportable diseases or unusual occurrences, as provided in Section 70737 of Title 22 of the California Code of Regulations. The department shall review Section 70737 of Title 22 of the California Code of Regulations requiring hospitals to report "unusual circumstances" and consider amending the section to enhance the clarity and specificity of this hospital reporting requirement.

SEC. 2. Section 1279.2 is added to the Health and Safety Code, to read:

1279.2. (a) (1) In any case in which the department receives a report from a facility pursuant to Section 1279.1, or a written or oral complaint involving a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250, that indicates an ongoing threat of imminent danger of death or serious bodily harm, the department shall make an onsite inspection or investigation within 48 hours or two business days, whichever is greater, of the receipt of the report or complaint and shall complete that investigation within 45 days.

(2) Until the department has determined by onsite inspection that the adverse event has been resolved, the department shall, not less than once a year, conduct an unannounced

inspection of any health facility that has reported an adverse event pursuant to Section 1279.1.

(b) In any case in which the department is able to determine from the information available to it that there is no threat of imminent danger of death or serious bodily harm to that patient or other patients, the department shall complete an investigation of the report within 45 days.

(c) The department shall notify the complainant and licensee in writing of the department's determination as a result of an inspection or report.

(d) For purposes of this section, "complaint" means any oral or written notice to the department, other than a report from the health facility, of an alleged violation of applicable requirements of state or federal law or an allegation of facts that might constitute a violation of applicable requirements of state or federal law.

(e) The costs of administering and implementing this section shall be paid from funds derived from existing licensing fees paid by general acute care hospitals, acute psychiatric hospitals, and special hospitals.

(f) In enforcing this section and Sections 1279 and 1279.1, the department shall take into account the special circumstances of small and rural hospitals, as defined in Section 124840, in order to protect the quality of patient care in those hospitals.

(g) In preparing the staffing and systems analysis required pursuant to Section 1266, the department shall also report regarding the number and timeliness of investigations of adverse events initiated in response to reports of adverse events.

SEC. 3. Section 1279.3 is added to the Health and Safety Code, to read:

1279.3. (a) By January 1, 2015, the department shall provide information regarding reports of substantiated adverse events pursuant to Section 1279.1 and the outcomes of inspections and investigations conducted pursuant to Section 1279.1, on the department's Internet Web site and in written form in a manner that is readily accessible to consumers in all parts of California, and that protects patient confidentiality.

(b) By January 1, 2009, and until January 1, 2015, the department shall make information regarding reports of substantiated adverse events pursuant to Section 1279.1, and outcomes of inspections and investigations conducted pursuant to Section 1279.1, readily accessible to consumers throughout California. The department shall also compile and make available, to entities deemed appropriate by the department, data regarding these reports of substantiated adverse events pursuant to Section 1279.1 and outcomes of inspections and investigations conducted pursuant to Section 1279.1, in order that these entities may post this data on their Internet Web sites. Entities deemed appropriate by the department shall enter into a memorandum of understanding with the department that requires the inclusion of all data and all hospital information provided by the department. These entities may include universities, consumer organizations, or health care quality organizations.

(c) The information required pursuant to this section shall include, but not be limited to, information regarding each substantiated adverse event, as defined in Section 1279.1, reported to the department, and may include compliance information history. The names of the health care professionals and health care workers shall not be included in the information released by the department to the public.

SEC. 4. Section 1280.4 is added to the Health and Safety Code, to read:

1280.4. If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 fails to report an adverse event pursuant to Section 1279.1, the department may assess the licensee a civil penalty in an amount not to exceed one hundred dollars ($100) for each day that the adverse event is not reported following the initial five-day period or 24-hour period, as applicable, pursuant to subdivision (a) of Section 1279.1. If the licensee disputes a determination by the department regarding alleged failure to report an adverse event, the licensee may, within 10 days, request a hearing pursuant to Section 100171. Penalties shall be paid when appeals pursuant to those provisions have been exhausted.

SEC. 5. This act shall become operative on July 1, 2007.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.